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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/511,972	02/24/2000	Boris Skurkovich	011-2 (53663-5004)	6154

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/511,972	SKURKOVICH ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41,43-62,64-95,98,100 and 101* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41, 45, 53-54, 62, 64, 72, 73, 80-81, 88-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-40,43,44,46-52,55-61,65-71,74-79,82-87,90-95,98,100 and 101.

DETAILED ACTION

1. Claims 1-41, 43-62, 64-95, 98, 100-101 are under consideration by the Examiner.

Election/Restrictions

2. Applicant's election of Group 43 (claims 41, 45, 53, 54, 62, 64, 72, 73, 80, 81, 88, 89) dated 9/22/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 45, 54, 64, 73, 81, 89 and amended claims 41, 53, 62, 72, 80, 88, (9/22/03) are under consideration by the Examiner.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite "a method of treating allergy by administering an anti-histamine antibody".

Claim objections

4. Claims 53-54 and 80-81 are objected to because of the following:

Claims 53-54 are objected to under 37 CFR 1.75 as being a substantial duplicates of claims 80-81, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim rejections-35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5a. Claims 41, 62, 88, are rejected under 35 U.S.C. § 103 as being unpatentable over Horsmanheimo et al (1996) in view of Wright et al (1992).

Horsmanheimo et al. discloses an increased histamine release in observed that suggests that histamine is involved in the early allergic response (see abstract, last 3 lines; Figure 1, page 410). Horsmanheimo et al. fail to disclose administering antibodies to the histamine produced in the allergic response.

Wright et al teaches that administration of antibodies is effective in immunotherapy because antibodies have structural and functional features that enhance their value in binding to antigens and can specifically block and inhibit antigens (see abstract, lines 5-7; and page 125, columns 1-2).

Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to use antihistamine antibodies as taught by Wright et al., to inhibit and block release of histamine which is involved in allergy as taught by Horsmanheimo with the expectation that the antibodies against histamine would be useful in treating the allergy in the mammal and would be used in immunotherapy.

5b. Claims 53, 72, 80 are rejected under 35 U.S.C. § 103 as being unpatentable over Horsmanheimo et al (1996) in view of Wright et al (1992) as applied to claims 41, 62, 88 above, and further in view of Stratagene (1988).

The teachings of Horsmanheimo et al (1996) and Wright et al (1992) have been set forth above in para 5a. However, the combined disclosure of these references do not teach the use of a kit in a method of treatment. The Stratagene catalog teaches a motivation to combine reagents of use into a kit (page 39, column 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the anti-histamine antibodies as taught by Horsmanheimo et al (1996) and Wright et al (1992) into a kit as taught by Stratagene since the Stratagene catalog teaches a motivation for combining reagents of use in any assay into a kit. It states that "Each kit provides two services: 1) a variety of different regents have been assembled and premixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 1

different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

5c. Claims 45, 64, 89 are rejected under 35 U.S.C. § 103 as being unpatentable over Horsmanheimo et al (1996) in view of Wright et al (1992) as applied to claims 41, 62, 88 above, and further in view of Snapper (1996).

The disclosure of Horsmanheimo et al (1996) and Wright et al (1992) have been set forth above in para 5a. However, Horsmanheimo et al (1996) and Wright et al (1992) fail to disclose administering interferon-γ together with an anti-histamine antibody in a method to treat allergy.

Snapper teaches that interferon-γ is a cytokine released predominantly by CD4+ T cells of the Th1 and Th0 type and administration of IFN-γ induces class switching from Th1 to Th2 type (page 325, see Introduction, first 4 lines). Furthermore, Snapper teaches that IFN-γ also inhibits IgE secretion by human peripheral blood mononuclear cells cultured with IL-4 indicating a role of IFN-γ in IgE responses in allergy (pages 332-333).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to administer IFN-γ as taught by Snapper with anti-histamine antibodies in a method of treating allergy as taught by Horsmanheimo et al (1996) and Wright et al (1992) with an expectation of success because Snapper teaches that IFN-γ inhibits IgE secretion, both IgE and IL-4 being involved in the allergic response.

5d. Claims 54, 73, 81, are rejected under 35 U.S.C. § 103 as being unpatentable over Horsmanheimo et al (1996) in view of Wright et al (1992) and Stratagene (1988) as applied to claims 52, 73, 80 above, and further in view of Snapper et al. (1981).

The disclosure of Horsmanheimo et al (1996), Wright et al (1992) and Stratagene (1988) have been set forth above (see paragraph 5b). However, the combined disclosure of these references do not explicitly teach a kit with anti-histamine antibodies and interferon-γ to be used in a method of treating allergy. The Stratagene catalog teaches a motivation to combine reagents of use into a kit (page 39, column 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to administer the anti-histamine antibodies as taught by Horsmanheimo et al (1996) and Wright et al (1992) with IFN-γ into a kit as taught by Stratagene and administer the contents of the kit in a method of treating allergy since the Stratagene catalog teaches a motivation for combining reagents of use in any assay into a kit. It states that "Each kit provides two services: 1) a variety of different regents have been assembled and premixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 1 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
October 9, 2003